GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:428
ANSWERED ON:23.07.2003
DISTINCTION BETWEEN A DRUG AND A DRUG INTERMEDIATE
BHASKAR RAO PATIL;CHARAN DAS MAHANT

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the technical and characteristic distinction between a Drug and a Drug Intermediate;

(b) the details of Drug Intermediates which are not used for human consumption and yetclassified as a drug under the registration policy of the Drug Controller of India;

(c) whether the Drug Controller of India has been vested with power to make exemption under the registration policy for import of drug intermediates;

(d) if so, the details thereof;

(e) whether Rifa S and Rifa SV used in manufacture of Rifamycin, a vital Anti TB drug has been classified as a drug intermediate by the Drug Controller of India; and

(f) if so, the reaction of the Government thereto ?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE(SHRI A.RAJA)

(a) & (b): Drugs are defined under Section 3 (b) of the Drugs and Cosmetics Act and include.

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(ii) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by Central Government by notification in the Official Gazette;

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board.

Drug Intermediates are materials produced during preparation of active ingredient. The Intermediates are not present in the finished drug product. Intermediates are `in-process materials` rather than drug substances or components in the finished drug product.

(c) & (d): Import Registration requirements are for drugs.

(e) & (f): The office of the DCG (I) has not received any application for the Import Registration of Rifa S and Rifa SV used in the manufacture of Rifampicin.